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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

VERINATA HEALTH, INC., and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, Plaintiffs, vs. ARIOSA DIAGNOSTICS, INC., and LABORATORY CORPORATION OF AMERICA HOLDINGS, Defendants.	Case No. 3:12-cv-05501-SI **DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFFS' CLAIMS FOR PATENT INFRINGEMENT AGAINST DEFENDANT LABORATORY CORPORATION OF AMERICA AND CLAIM FOR ENHANCED DAMAGES AGAINST ALL DEFENDANTS** Date: February 22, 2013 Time: 9:00 a.m. Courtroom: 10, 19th Floor

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I. INTRODUCTION

Plaintiffs quietly acknowledge (in footnote 2 of their Opposition) that they had no basis to plead their claim for enhanced damages against Ariosa or LabCorp in the First Amended Complaint ("FAC"). This comes as no surprise, given that Ariosa and LabCorp first received notice of Plaintiffs' infringement claims by virtue of this lawsuit, just a few days after the issuance of each patent. *In re Seagate Tech., LLC*, 497 F.3d 1360, 1374 (Fed. Cir. 2007) ("in ordinary circumstances, willfulness will depend on an infringer's prelitigation conduct … when a complaint is filed, a patentee must have a good faith basis for alleging willful infringement. So a willfulness claim asserted in the original complaint must necessarily be grounded exclusively in the accused infringer's pre-filing conduct.") While Plaintiffs purport to reserve the right to seek leave to amend at some later date, they fail to suggest any facts that, if discovered, would entitle them to pursue claims of willful infringement. Plaintiffs' claims for enhanced damages should be dismissed, as Plaintiffs themselves request.

Moreover, Plaintiffs cannot cure the pleading deficiencies in their claims of **direct** infringement against LabCorp. Although Plaintiffs offer to make "minor amendments" to specifically plead that LabCorp "sells" and "offers to sell" the Harmony Test, (D.I. 28 at p. 3, n. 3), they make no such offer to specifically plead that LabCorp "makes" or "uses" the Harmony Test, preferring instead to rely on their oblique allegation that LabCorp is "practicing one or more claims" of the patents-in-suit. (D.I. 22 at ¶¶ 20, 28.) This is insufficient to state a claim of direct infringement, as made clear by Form 18 to Federal Rule of Civil Procedure 84. Fed. R. Civ. P. 84.

Plaintiffs cite to no allegations in their FAC providing any plausible basis for a reasonable inference *that LabCorp itself* "makes" or "uses" the Harmony Test. Instead, they wildly exaggerate language from the Ariosa Press Release to support this inference—that Ariosa and LabCorp "together" are "committed to ensuring that the latest advances in prenatal testing are accessible to all healthcare providers and women," and that the Harmony Test "will be available in the United States and Canada through" LabCorp. This language says nothing about whether LabCorp itself "makes" or "uses" the Harmony Test and is no substitute for the language required by Form 18. The Ariosa Press Release identifies only one service performed by LabCorp itself—

the drawing of blood at its patient service centers—and Plaintiffs do not argue that this act alone would support a claim that LabCorp itself "makes" or "uses" the Harmony Test.

The reason that Plaintiffs do not even offer to amend their pleading to specifically allege that LabCorp "makes" or "uses" the Harmony Test is that they know they cannot in good faith assert any such claim. The extrinsic evidence upon which Plaintiffs improperly rely—a physician's brochure found on LabCorp's website ("the Brochure")—expressly undermines any such claim: "The Harmony Prenatal Test has been developed and *is performed as a laboratory test service by Ariosa Diagnostics*, a CLIA-certified clinical laboratory." (D.I. 28, Walter Decl. at Ex. 1, p. 7.) In short, Plaintiffs know that Ariosa, not LabCorp, performs the Harmony Test at its CLIA-certified clinical laboratory. They have no basis to make any contrary allegation in a future pleading.

Because Plaintiffs cannot allege that LabCorp itself "makes" or "uses" the Harmony Test, they also cannot plead direct infringement by alleging that LabCorp "sells" or "offers to sell" the Harmony Test, irrespective of whether they were to amend their FAC to use these express words. This is because, as explained in detail in our moving papers, a party cannot incur liability for direct infringement by offering to sell a method performed by another party. Plaintiffs cite no contrary authority—and none exists.

Nor do Plaintiffs provide any justification for their hollow allegation of contributory infringement against LabCorp—which does not even identify the "material components" that LabCorp supplies to Ariosa. While Plaintiffs concede in their Opposition that the blood samples that LabCorp transmits to Ariosa are the unidentified "material components," (*see* D.I. 28 at p. 8), they offer no basis to suggest that these blood samples have no substantial non-infringing use. Indeed, even Plaintiffs concede that "it may be true as a general matter that different types of tests can be performed on blood …." (D.I. 28 at p. 8.) Instead, they offer speculation that LabCorp *might* treat or package the blood samples in a way that *might* support a claim for contributory infringement—even though the FAC contains no allegations of any special treatment or packaging. Plaintiffs cannot ground their contributory infringement claim on speculation that they have failed to include, and would have no basis to include, in their pleading (and that, in fact, is

contrary to reality, as Verinata well knows as a competitor in the field with its own laboratory partner, PerkinElmer).[1]

Finally, in an effort to bolster their indirect "inducement" claim against LabCorp, Plaintiffs improperly rely upon extrinsic evidence gleaned from the Brochure that they argue purportedly demonstrates LabCorp's detailed knowledge of Ariosa's technology. It is well-established, however, that knowledge of another's process is not tantamount to inducement to infringe a patent, even if the Court were to rely upon this extrinsic evidence. Plaintiffs do not, because they cannot, point to any allegation in their FAC—or even a statement in the Brochure—that satisfies the requirements of pleading a claim for inducing infringement—facts that allow a reasonable inference that LabCorp specifically intended Ariosa to infringe the patents-in-suit and knew that Ariosa's acts would constitute infringement.

II. ARGUMENT

A. Plaintiffs Do Not and Cannot Allege Direct Infringement by LabCorp

1. Plaintiffs Do Not and Cannot Allege that LabCorp Itself "Makes" or "Uses" the Harmony Test

Plaintiffs never defend their failure to expressly allege that LabCorp itself "makes" or "uses" the Harmony Test. Indeed, they do not even offer to amend their FAC to include this express allegation. Instead, Plaintiffs seize upon the word "together" as it appears in the Ariosa Press Release to conjure the possibility that LabCorp itself performs the Harmony Test. The full quotation in which that word appears provides no plausible support for that inference: "'The Harmony Prenatal Test is an affordable, high-quality test that provides a new choice for women,'" said Dr. Song [Ariosa's CEO]. (D.I. 27, Gindler Decl. Ex. 1.) "'Together with LabCorp, we are committed to ensuring that the latest advances in prenatal testing are accessible to all healthcare providers and women.'" *Id.* Sharing a commitment to accessible healthcare is not equivalent to performing an infringing act.

[1] *See* www.verinata.com/news/perkinelmer-and-verinata-health-announce-collaboration-to-expand-access-to-non-invasive-prenatal-test-for-down-syndrome-and-other-chromosomal-abnormalities (last visited Feb. 6, 2013).

Similarly, Plaintiffs belabor the statement indicating that the Harmony Test "will be available through" LabCorp, reinterpreting this language to suggest that LabCorp actually runs the Harmony Test itself. (D.I. 28 at pp. 1, 3, 6.) Yet neither the FAC nor the Ariosa Press Release *actually* states or suggests that LabCorp itself performs the Harmony Test. The only factual description of LabCorp's role that can be found in the Ariosa Press Release is of a "maternal blood draw taken at a doctor's office or patient service center"—and drawing blood does not constitute a *single step* of the patented claims. (D.I. 27, Gindler Decl., Ex. 1.) Yet, in order for LabCorp to directly infringe the patents-in-suit, it must perform *all* of the steps of the claimed methods. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328 (Fed. Cir. 2008) ("The law of this circuit is axiomatic that a method claim is directly infringed only if each step of the claimed method is performed").

Moreover, the Brochure itself establishes that Plaintiffs cannot amend their pleading to state a claim of direct infringement. The last page of the Brochure clearly states that Ariosa, not LabCorp, performs the Harmony Test: "The Harmony Prenatal Test has been developed and *is performed as a laboratory test service by Ariosa Diagnostics*, a CLIA-certified clinical laboratory." (D.I. 28, Walter Decl., Ex. 1 at p. 7) The only LabCorp procedure listed in the Brochure is "one blood draw performed at 10 weeks or later in pregnancy." *Id.* Plaintiffs' creative reading of the Ariosa Press Release cannot defeat these simple truths—truths that Plaintiffs would have this Court ignore. In short, Plaintiffs have failed to plead, and cannot amend to plead, a claim that LabCorp itself "makes" or "uses" the Harmony Test.

2. LabCorp's Sale of, or Offer to Sell, Ariosa's Performance of the Harmony Test Cannot Infringe Plaintiffs' Patented Methods

In an effort to rescue their pleading, Plaintiffs point to language in the FAC that they argue should be interpreted to allege that LabCorp is offering the Harmony Test for sale. (D.I 28 at pp. 2-5.) Even if the FAC could be interpreted in that way, and even if it were amended to make that express allegation, it would make no difference. This is because LabCorp's sale of, or offer to sell, Ariosa's performance of the Harmony Test *cannot* directly infringe the patents-in-suit, which contain only method claims. Method claims may only be infringed by performing them. *Joy*

Technologies, Inc. v. Flakt, Inc., 6 F.3d 770, 773 (Fed. Cir. 1993). According to the Federal Circuit, "Congress has consistently expressed the view that it understands infringement of method claims under section 271(a) to be limited to use." *NTP, Inc. v. Research in Motion, Ltd.*, 418 F. 3d 1282, 1319 (Fed. Cir. 2005). Accordingly, many District Courts have held that a party's sale or offer to sell a method, absent performance of the method *by that party*, does not constitute an act of infringement under 35 U.S.C. § 271(a).[2] *No court* has held that a party can directly infringe a method claim by selling someone else's performance of it. Plaintiffs' reliance upon cases holding that sale of method can directly infringe misses this key point from those cases; the seller itself must also *perform* the method in order to directly infringe it.

The cases Plaintiffs cite in support of their view are therefore inapposite. For example, in *WesternGeco L.L.C. v. ION Geophysical Corp.*, a defendant who sold equipment used to perform a patented method did not directly infringe, because it was "clear that the alleged infringer must sell the *performance of the process itself* in order for the sale to be actionable as direct infringement." 869 F. Supp. 2d 793, 799 (S.D. Tex. 2012), *rev'd in part by* 4:09-CV-1827, 2012 WL 1708852 (S.D. Tex. May 15, 2012). In refusing to dismiss claims against a second defendant accused of infringing by selling a method, the court noted that "had the … Defendants submitted evidence demonstrating that their offers were offers to perform *only some of the steps* comprising [Plaintiff's] method claims, then summary judgment would be appropriate in favor of Defendants." *Id.* Similarly, in *Optigen, LLC v. Int'l Genetics, Inc.*, the accused defendants, allegedly dominated by a single defendant, were accused of selling *and* performing the infringing method. *Optigen, LLC v. Int'l Genetics, Inc.*, 777 F. Supp. 2d 390, 394 (N.D.N.Y. 2011) ("[a contractor] then forwards the sample to [defendant] in The Bahamas for performance of tests that

[2] *See Transocean Offshore Deepwater Drilling, Inc. v. GlobalSantaFe Corp.*, 400 F. Supp. 2d 998, 1012 (S.D. Tex. 2005) ("The Federal Circuit has long held that a method claim is infringed only when the method is used or practiced. The court is not persuaded that the 'offers to sell' language added to § 271(a) … allows a patent holder to sue a competitor for infringement of method claims at an earlier stage than previously allowed"); *W.L. Gore & Associates, Inc. v. Medtronic, Inc.*, 2:10-CV-441, 2012 WL 2308651 at *14 (E.D. Va. June 18, 2012) ("since the Federal Circuit appears to have concluded that [the sell or offer to sell] prong does not apply to method claims, … it appears the proper course is for this Court to consider infringement only under 271(g).")

infringe the [patents].") The same was true in *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, wherein the declaratory judgment plaintiff actually performed the service it offered to member banks. 667 F. Supp. 2d 29, 32 (D.D.C. 2009) ("CLS provides the CLS Service to banks known as CLS Bank Settlement Members.") No such allegations are made, or could be made, by Plaintiffs.

B. Plaintiffs Do Not and Cannot Plead a Claim of Contributory Infringement Against LabCorp

Having mechanically alleged in their FAC that LabCorp "continues to supply to Ariosa material components of the Harmony Prenatal Test having no substantial non-infringing use," (D.I. 22 at ¶ 15; *see also* D.I. 22 ¶¶ 22, 30), Plaintiffs now profess confusion as to "what more should be required" to meet their pleading obligations. (D.I. 28 at p. 7). Yet Plaintiffs deliberately disregard those authorities that explain *exactly* what is required to plead contributory infringement in this District—*facts* indicating "whether the accused products can be used for purposes other than infringement." *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323,1338 (Fed. Cir. 2012).

In this vein, Plaintiffs might have started by naming the "material component" itself in their FAC; an 8-10mL whole blood sample. (D.I. 28, Walter Decl., Ex. 1 at p. 7.) Yet Plaintiffs' FAC does not even bother to identify this component, for the obvious reason that there are many non-infringing uses for blood samples. Plaintiffs justify this deficiency by turning to a smorgasbord of case law decided without the benefit of the Federal Circuit's guidance in *Bill of Lading*.[3] Even if threadbare allegations such as those recited by the Plaintiffs may have been sufficient to plead contributory infringement before *Bill of Lading*, they do not pass muster in this District today.

The standard recited in *In re Bill of Lading* echoes 35 U.S.C. § 271(c), wherein an accused contributory infringer must supply a component "knowing the same to be especially made or *especially adapted for use in an infringement* of such patent, and not a *staple article* or commodity

[3] *See Nielson Co. (US), LLC v. ComScore, Inc.*, 819 F. Supp. 2d 589 (E.D. Va. 2011); *Cascades Computer Innovation, LLC v. Sony-Ericsson Mobile Commc'ns (USA) Inc.*, No. 11-7223, 2012 WL 1377053 (N.D. Ill. Apr. 18, 2012); *Rambus, Inc. v. Nvidia Corp.*, No. 08-0334, 2008 WL 4911165 (N.D. Cal. Nov. 13, 2008).

of commerce suitable for substantial noninfringing use." 35 U.S.C. § 271(c) (emphasis added). Plaintiffs give examples of "open issues" concerning those blood samples, such as their volume, packaging, or any chemical or physical optimizations made to them. (D.I. 28 at p. 8.) This is little more than an open confession of the reason that Plaintiffs did not identify the blood samples as the "material components" in their FAC—they are not aware of anything about them that would support an allegation that they have no substantial non-infringing use.

Plaintiffs make much of the fact that the "only product Ariosa has is the Harmony test," but this is of no consequence in the inquiry of substantial non-infringing use. (D.I. 28 at 2, 8.) Even situations where "practicing the patented method may be the most logical or useful purpose for [defendant's] products [do] not render the alternative uses unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *In re Bill of Lading*, 681 F.3d 1338 (citing *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009)) (internal quotation marks omitted). As is well known, and not subject to reasonable dispute, there is an enormous universe of substantial non-infringing uses for whole blood samples (as would be evident to anyone who has an annual physical examination). Fed. R. Evid. 201(b); *See Sherman v. Stryker Corp.*, SACV 09-224JVS(ANX), 2009 WL 2241664 at *2 (C.D. Cal. Mar. 30, 2009) ("the Court may take judicial notice of matters of public record if the facts are not subject to reasonable dispute"). For these reasons, Plaintiffs' claim for contributory infringement should be dismissed without leave to amend.

C. Plaintiffs Do Not and Cannot Plead a Claim for Inducing Infringement Against LabCorp

To plead inducement to infringe, Plaintiffs must allege facts allowing an inference that LabCorp specifically intended Ariosa to infringe the patents-in-suit, and knew that Ariosa's acts would constitute infringement. *In re Bill of Lading* , 681 F.3d at 1339. Plaintiffs argue that the Brochure and Ariosa Press Release suggest that LabCorp "fully understands the details of the infringing conduct they are inducing Ariosa to perform." (D.I. 28 at p. 10.) However, even if the FAC could be construed to allege that LabCorp has detailed knowledge of the Harmony Test, intent to cause infringement cannot be inferred from such knowledge. Mere knowledge of possible

infringement by others is not tantamount to inducement; specific intent and action *to induce infringement* must also be shown. *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F. 3d 1293, 1306 (Fed. Cir. 2006) ("inducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities").

Nothing in the FAC suggests that LabCorp has played a role in directing or instructing Ariosa in how to perform the test in an infringing manner. Indeed, it would be impossible for Plaintiffs to have made any such allegation—or for any inference to that effect to be drawn from the FAC—given that the Ariosa Press Release, on which they heavily rely in their Opposition, describes the Harmony Test as Ariosa's "proprietary technology." (D.I. 27, Gindler Decl., Ex. 1.) The same is true of the Brochure, which states in no uncertain terms that the "Harmony Prenatal Test has been developed and is performed as a laboratory test service by Ariosa Diagnostics." Accordingly, Plaintiffs do not, and cannot, plead any plausible claim against LabCorp that it induces Ariosa to infringe.

III. CONCLUSION

Plaintiffs' improper use of new factual matter serves only to accentuate the emptiness of their claims against LabCorp. These defects cannot be cured through any amendment. All claims against LabCorp should be dismissed without leave to amend.

Dated: February 6, 2013

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